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John Rose

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9169

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EXAMINER

PEPITONE, MICHAEL F

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Response to Arguments

The amendments to the claims will not be entered because the scope of the claims is changed; new issues are raised which would require a further search and/or consideration. Applicant's arguments are directed to subject matter that requires further search and consideration.

While arguments to the not entered amendments will not be addressed below, applicant's arguments pertaining to the finally rejected claims will be discussed for further clarification.

Gogolewski *et al.* (US '341) discloses resorbable poly(DL-lactide co-glycolide) copolymers (2:48-59) having a Young's modulus of 1 to 50 GPa and a tensile strength of 0.1 to 20 GPa (2:38-42).

Yuan *et al.* (US '697) discloses the modulus of a 10/90 PLA/PGA fiber to be 1.83 E 10 Pa {18.3 GPa}, measured using a DMA {dynamic mechanical analyzer} (11:55-12:18). Yuan *et al.* (US '697) also discloses tensile modulus and tensile strength of 14.5 GPa and 992 MPa, respectively {Table 2}, however, it is unclear how these measurements were obtained. While these numerical values are different from the claimed values {instant claim 1}, one having ordinary skill in the art understands that test protocol, as well as which technique used to obtain tensile properties, will yield different numerical values, even if an identical sample was employed in each measurement. For example, the instant specification {paragraph numbers from PG-PUB} discloses an Instron 5566 machine with a 100 N load cell was employed to determine the tensile properties (§ 42). However, it is unclear of the parameters used during the tensile testing. For example, the temperature of the test and the crosshead speed of the Instron {i.e. the standard used to conduct the measurement} were not indicated. Evidence would need to

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be presented to support applicant's position that the 10/90 PLA/PGA fibers of example 1 disclosed in Yuan *et al.* (US '697) (10:6-67), when tested under similar conditions {on an Instron 5566 machine with a 100 N load cell (§ 42)} would yield tensile data below the claimed values. While the preferred example of 10/90 PLA/PGA does not show tensile modulus and tensile strength of 20 GPa and 1100 MPa, respectively, the reference must be considered for all that it discloses and must not be limited to preferred embodiments [see MPEP 2123].

Jamiolkowski *et al.* (US 4,700,704) was relied on for quenching melt spun copolymers of glycolide and caprolactone via extrusion into a quench bath {ice water} prior to drawing (1:10-16; 9:44-55), as such glycolide copolymer monofilaments prepared with a quench bath provide synthetic surgical articles having desirable tensile strength, controllable absorbability, and suitable in vivo strengths (2:23-33).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Jamiolkowski *et al.* (US '704) suggests that glycolide copolymer monofilaments prepared with a quench bath provide synthetic surgical articles having desirable tensile strength, controllable absorbability, and suitable in vivo strengths (2:23-33).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on

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obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Okuzaki *et al.* (*Journal of Polymer Science: Part B: Polymer Physics* **1999**, 37, 991-996) was relied on for zone drawing of biosorbable polymers {PLLA fibers} (pg. 991) as zone drawing affords fibers having high orientation with minimal thermal degradation or oxidation occurring (pg. 991).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL PEPITONE whose telephone number is (571)270-3299. The examiner can normally be reached on M-F, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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MFP
13-April-09

/Harold Y Pyon/
Supervisory Patent Examiner, Art Unit
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